

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

11 DEC 2005

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Applicant's or agent's file reference 113926:MPO:LK:kf	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/AU2004/001783	International filing date (<i>day/month/year</i>) 17 December 2004	Priority date (<i>day/month/year</i>) 19 December 2003	
International Patent Classification (IPC) or national classification and IPC <div style="display: flex; justify-content: space-between;"> Int. Cl. C12N 15/31 (2006.01) A61K 39/02 (2006.01) A61P 1/12 (2006.01) </div> <div style="display: flex; justify-content: space-between;"> A61K 38/04 (2006.01) A61K 48/00 (2006.01) </div> <div style="display: flex; justify-content: space-between;"> A61K 38/16 (2006.01) A61P 1/00 (2006.01) </div>			
Applicant MURDOCH UNIVERSITY et al			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 4 sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: <div style="margin-left: 20px;"> a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of 1 sheets, as follows: <div style="margin-left: 20px;"> <input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. </div> </div> <div style="margin-left: 20px;"> b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions). </div>	
4. This report contains indications relating to the following items: <div style="margin-left: 20px;"> <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application </div>	

Date of submission of the demand 18 October 2005	Date of completion of this report 01 January 2006
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer ANDREW ACHILLEOS Telephone No. (02) 6283 2280

Box No. I Basis of the report1. With regard to the **language**, this report is based on:

- ☒ The international application in the language in which it was filed
- ☐ A translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3(a) and 23.1 (b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages **1-77** as originally filed/furnished
- pages* received by this Authority on _____ with the letter of _____
- pages* received by this Authority on _____ with the letter of _____
- ☒ the claims:
- pages **79-82** as originally filed/furnished
- pages* as amended (together with any statement) under Article 19
- pages* **78** received by this Authority on **18 October 2005** with the letter of **18 October 2005**
- pages* received by this Authority on _____ with the letter of _____
- ☒ the drawings:
- pages **1/13-13/13** as originally filed/furnished
- pages* received by this Authority on _____ with the letter of _____
- pages* received by this Authority on _____ with the letter of _____
- ☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 1-26	YES
	Claims	NO
Inventive step (IS)	Claims 1-26	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-26	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

Novelty and Inventive Step

The documents cited in the ISR do not clearly and unmistakably disclose the applicant's polypeptide as defined in the amended claims. Therefore, claims 1-26 are novel and involve an inventive step.

Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
 - a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☒ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☒ filed together with the international application in electronic form
 - ☐ furnished subsequently to this Authority for the purposes of search and/or examination
 - ☐ received by this Authority as an amendment* on
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."

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The Claims Defining the Invention are as Follows

1. An isolated polypeptide comprising:

- 5 (i) an amino acid sequence selected from the group consisting of
SEQ ID NO:2, SEQ ID NO:4 to SEQ ID NO:6, and SEQ ID NO:8
to SEQ ID NO:22;
- (ii) an amino acid sequence which is at least 60% homologous to an
amino acid sequence from (i);
- (iii) an amino acid sequence which is at least 80% identical to an
amino acid sequence from (i); or
- 10 (iv) a fragment of any of (i) to (iii) with a biological activity of the
polypeptide encoded by SEQ ID NO:2.

2. An isolated polynucleotide comprising:

- (i) a nucleotide sequence encoding a polypeptide according to claim
1;
- 15 (ii) the nucleotide sequence set out in SEQ ID NO:1;
- (iii) a nucleotide sequence corresponding to a degenerate version of
the sequences defined in (i) or (ii);
- (iv) a nucleotide sequence capable of selectively hybridising to the
sequences in (i) to (iii);
- 20 (v) a nucleotide sequence complementary to any of the sequences (i)
to (iv).
- (vi) a fragment of the sequence in (v) suitable for use as a primer or
probe.

25 3. A method for preparing a polypeptide according to claim 1 comprising the
steps of: